

# SENATE BILL 133

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CF HB 316

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By: **Senator Conway**

Introduced and read first time: January 18, 2012

Assigned to: Education, Health, and Environmental Affairs

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Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: February 29, 2012

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **State Board of Pharmacy – Wholesale Distributor Permits – Permit and**  
3 **Application Requirements**

4 FOR the purpose of exempting a manufacturer that distributes its own prescription  
5 devices that are approved or authorized by the U.S. Food and Drug  
6 Administration from certain permit requirements; altering the information  
7 required to be included in an application for a wholesale distributor permit;  
8 limiting a requirement that the State Board of Pharmacy or its designee  
9 conduct a certain inspection to apply only to applicants that hold prescription  
10 drugs or devices; altering certain requirements for a criminal history records  
11 check of a designated representative and the supervisor of a designated  
12 representative of an applicant; making stylistic changes; and generally relating  
13 to application requirements for a wholesale distributor permit issued by the  
14 State Board of Pharmacy.

15 BY repealing and reenacting, without amendments,  
16 Article – Health Occupations  
17 Section 12–6C–05(a), (c), and (h)  
18 Annotated Code of Maryland  
19 (2009 Replacement Volume and 2011 Supplement)

20 BY repealing and reenacting, with amendments,  
21 Article – Health Occupations  
22 Section 12–6C–03(b) and 12–6C–05(b) and (d)  
23 Annotated Code of Maryland

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 (2009 Replacement Volume and 2011 Supplement)

2 BY repealing

3 Article – Health Occupations

4 Section 12–6C–05(e)

5 Annotated Code of Maryland

6 (2009 Replacement Volume and 2011 Supplement)

7 BY adding to

8 Article – Health Occupations

9 Section 12–6C–05(e) and 12–6C–05.1

10 Annotated Code of Maryland

11 (2009 Replacement Volume and 2011 Supplement)

12 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
13 MARYLAND, That the Laws of Maryland read as follows:

14 **Article – Health Occupations**

15 12–6C–03.

16 (b) (1) A manufacturer engaged in wholesale distribution shall hold a  
17 wholesale distributor permit issued under this subtitle.

18 (2) Notwithstanding paragraph (1) of this subsection, the information  
19 and qualification requirements for obtaining a permit under this subtitle, beyond that  
20 required by federal law, do not apply to [a]:

21 (I) A manufacturer [who] THAT distributes its own prescription  
22 drugs THAT ARE approved by the U.S. Food and Drug Administration; OR

23 (II) A MANUFACTURER THAT DISTRIBUTES ITS OWN  
24 PRESCRIPTION DEVICES THAT ARE APPROVED OR AUTHORIZED BY THE U.S.  
25 FOOD AND DRUG ADMINISTRATION.

26 12–6C–05.

27 (a) To apply for a wholesale distributor permit, an applicant shall:

28 (1) Pay to the Board an application fee set by the Board; and

29 (2) Submit an application to the Board on the form that the Board  
30 requires.

31 (b) The application shall include the following:

- 1           (1)    The name, full business address, and telephone number of the  
2 applicant;
- 3           (2)    All trade or business names used by the applicant;
- 4           (3)    Addresses, telephone numbers, and the names of contact persons  
5 for the facility used by the applicant for the storage, handling, and distribution of  
6 prescription drugs;
- 7           (4)    The type of business form under which the applicant operates,  
8 such as partnership, corporation, or sole proprietorship;
- 9           (5)    The name of each owner and operator of the applicant, including:
- 10                   (i)    If an individual, the name of the individual;
- 11                   (ii)   If a partnership, the name of the partnership and of each  
12 partner;
- 13                   (iii)   If a corporation, the name of the corporation, the name and  
14 title of each corporate officer and director, and the state of incorporation; and
- 15                   (iv)   If a sole proprietorship, the full name of the sole proprietor  
16 and the name of the sole proprietor's business entity;
- 17           (6)    A list of all licenses and permits issued to the applicant by any  
18 other state that authorizes the applicant to purchase or possess prescription drugs;
- 19           (7)    For the designated representative and the immediate supervisor of  
20 the designated representative at the applicant's place of business, **THE FOLLOWING:**
- 21                   [(i)    Fingerprints necessary to conduct a criminal history records  
22 check; and
- 23                   (ii)    The following:
- 24                           1.] **(I)**        Name;
- 25                           [2.] **(II)**       Places of residence for the past 7 years;
- 26                           [3.] **(III)**      Date and place of birth;
- 27                           [4.] **(IV)**      The name and address of each business where  
28 the individual was employed during the past 7 years, and the individual's job title or  
29 office held at each business;

1 [5.] (V) A statement of whether, during the past 7  
2 years, the individual has been the subject of any proceeding for the revocation of any  
3 professional or business license or any criminal violation and, if so, the nature and  
4 disposition of the proceeding;

5 [6.] (VI) A statement of whether, during the past 7  
6 years, the individual has been enjoined, either temporarily or permanently, by a court  
7 of competent jurisdiction from violating any federal or state law regulating the  
8 possession, control, or distribution of prescription drugs, together with details  
9 concerning the event;

10 [7.] (VII) A description of any involvement, including any  
11 investments other than the ownership of stock in a publicly traded company or mutual  
12 fund, by the individual during the past 7 years with any business that manufactures,  
13 administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in  
14 which the business was named as a party;

15 [8.] (VIII) [A.] 1. A description of any misdemeanor  
16 or felony offense of which the individual, as an adult, was found guilty, regardless of  
17 whether adjudication of guilt was withheld or whether the individual pled guilty or  
18 nolo contendere; and

19 [B.] 2. If the individual indicates that a criminal  
20 conviction is under appeal and submits a copy of the notice of appeal, within 15 days  
21 after the disposition of the appeal, a copy of the final written order of disposition; and

22 [9.] (IX) A photograph of the individual taken in the  
23 previous 180 days.

24 (c) The information required under subsection (b) of this section shall be  
25 provided under oath.

26 (d) The Board may not issue a wholesale distributor permit to an applicant  
27 unless the Board or its designee:

28 (1) **[Conducts] IF THE APPLICANT HOLDS PRESCRIPTION DRUGS**  
29 **OR DEVICES, CONDUCTS** a physical inspection of the applicant's place of business,  
30 including any facility of the applicant;

31 (2) Finds that the place of business and facility, if any, meets the  
32 Board's requirements;

33 (3) Determines that the designated representative of the applicant  
34 meets the following qualifications:

35 (i) Is at least 21 years of age;

1 (ii) Has been employed full time for at least 3 years in a  
2 pharmacy or with a wholesale distributor in a capacity related to the dispensing and  
3 distribution of, and record keeping relating to, prescription drugs;

4 (iii) Is employed by the applicant full time in a managerial level  
5 position;

6 (iv) Is actively involved in and aware of the daily operation of  
7 the wholesale distributor;

8 (v) Is physically present, except for an authorized absence such  
9 as sick leave or vacation leave, at the facility of the applicant during regular business  
10 hours;

11 (vi) Is serving as a designated representative for only one  
12 applicant at a time, or for two or more wholesale distributors who are located in the  
13 same facility and are members of an affiliated group, as defined in § 1504 of the  
14 Internal Revenue Code;

15 (vii) Does not have any convictions for a violation of any federal,  
16 state, or local laws relating to wholesale or retail prescription drug distribution or  
17 distribution of controlled substances; and

18 (viii) Does not have any convictions for a felony under federal,  
19 state, or local laws; and

20 (4) Determines that the immediate supervisor of the designated  
21 representative of the applicant meets the following qualifications:

22 (i) Is at least 21 years of age;

23 (ii) Has been employed full time for at least 3 years in a  
24 pharmacy or with a wholesale distributor in a capacity related to the dispensing and  
25 distribution of, and record keeping relating to, prescription drugs;

26 (iii) Is employed by the applicant full time in a managerial level  
27 position;

28 (iv) Is actively involved in and aware of the daily operation of  
29 the wholesale distributor;

30 (v) Does not have any convictions for a violation of any federal,  
31 state, or local laws relating to wholesale or retail prescription drug distribution or  
32 distribution of controlled substances; and

1 (vi) Does not have any convictions for a felony under federal,  
2 state, or local laws.

3 [(e) (1) In this subsection, “Central Repository” means the Criminal  
4 Justice Information System Central Repository of the Department of Public Safety and  
5 Correctional Services.

6 (2) In accordance with the requirements of this subsection, the Board  
7 shall submit the fingerprints provided with a permit application to the Central  
8 Repository for a State and national criminal history records check of the designated  
9 representative and the immediate supervisor of the designated representative.

10 (3) As part of an application to the Central Repository for a State and  
11 national criminal history records check, the Board shall submit to the Central  
12 Repository:

13 (i) Two complete sets of legible fingerprints taken on forms  
14 approved by the director of the Central Repository and the Director of the Federal  
15 Bureau of Investigation;

16 (ii) The fee authorized under § 10–221(b)(7) of the Criminal  
17 Procedure Article for access to State criminal history records; and

18 (iii) The processing fee required by the Federal Bureau of  
19 Investigation for a national criminal history records check.

20 (4) In accordance with §§ 10–201 through 10–228 of the Criminal  
21 Procedure Article, the Central Repository shall forward to the Board and to the  
22 applicant the criminal history record information of the applicant.

23 (5) Information obtained from the Central Repository under this  
24 subsection:

25 (i) Shall be confidential;

26 (ii) May not be disseminated; and

27 (iii) Shall be used only for the permitting purpose authorized by  
28 this subtitle.

29 (6) The subject of a criminal history records check under this  
30 subsection may contest the contents of the printed statement issued by the Central  
31 Repository as provided in § 10–223 of the Criminal Procedure Article.]

32 **(E) THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE**  
33 **SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL**

1 SUBMIT TO A CRIMINAL HISTORY RECORDS CHECK IN ACCORDANCE WITH  
2 **§ 12-6C-05.1** OF THIS SUBTITLE.

3 (h) Within 30 days after the date the Board receives a completed application,  
4 including the results of all required criminal history records checks, the Board shall  
5 notify the applicant of the Board's acceptance or rejection of the application.

6 **12-6C-05.1.**

7 (A) (1) IN THIS SUBSECTION, "CENTRAL REPOSITORY" MEANS THE  
8 CRIMINAL JUSTICE INFORMATION SYSTEM CENTRAL REPOSITORY OF THE  
9 DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONAL SERVICES.

10 (2) THIS SUBSECTION APPLIES TO APPLICANTS LOCATED IN THE  
11 STATE.

12 (3) AS PART OF AN APPLICATION TO THE CENTRAL REPOSITORY  
13 FOR A STATE AND NATIONAL CRIMINAL HISTORY RECORDS CHECK, THE  
14 DESIGNATED REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE  
15 DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL SUBMIT TO THE  
16 CENTRAL REPOSITORY:

17 (I) TWO COMPLETE SETS OF LEGIBLE FINGERPRINTS  
18 TAKEN ON FORMS APPROVED BY THE DIRECTOR OF THE CENTRAL REPOSITORY  
19 AND THE DIRECTOR OF THE FEDERAL BUREAU OF INVESTIGATION;

20 (II) THE FEE AUTHORIZED UNDER § 10-221(B)(7) OF THE  
21 CRIMINAL PROCEDURE ARTICLE FOR ACCESS TO STATE CRIMINAL HISTORY  
22 RECORDS; AND

23 (III) THE PROCESSING FEE REQUIRED BY THE FEDERAL  
24 BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL HISTORY RECORDS  
25 CHECK.

26 (4) IN ACCORDANCE WITH §§ 10-201 THROUGH 10-228 OF THE  
27 CRIMINAL PROCEDURE ARTICLE, THE CENTRAL REPOSITORY SHALL FORWARD  
28 THE CRIMINAL HISTORY RECORDS INFORMATION OF THE DESIGNATED  
29 REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED  
30 REPRESENTATIVE OF AN APPLICANT TO THE BOARD AND THE APPLICANT.

31 (5) THE BOARD SHALL ENSURE THAT INFORMATION OBTAINED  
32 FROM THE CENTRAL REPOSITORY UNDER THIS SUBSECTION:

33 (I) IS KEPT CONFIDENTIAL;

1 (II) IS NOT REDISSEMINATED; AND

2 (III) IS USED ONLY FOR THE PERMITTING PURPOSE  
3 AUTHORIZED BY THIS SUBTITLE.

4 (6) THE SUBJECT OF A CRIMINAL HISTORY RECORDS CHECK  
5 UNDER THIS SUBSECTION MAY CONTEST THE CONTENTS OF THE PRINTED  
6 STATEMENT ISSUED BY THE CENTRAL REPOSITORY AS PROVIDED IN § 10-223  
7 OF THE CRIMINAL PROCEDURE ARTICLE.

8 (B) (1) THIS SUBSECTION APPLIES TO APPLICANTS LOCATED  
9 OUTSIDE THE STATE.

10 (2) THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE  
11 SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL  
12 SUBMIT TO A CRIMINAL HISTORY RECORDS CHECK BY THE APPLICANT'S STATE  
13 OF RESIDENCE, IN ACCORDANCE WITH THE LAWS OF THE APPLICANT'S STATE  
14 OF RESIDENCE.

15 (3) THE CRIMINAL HISTORY RECORDS CHECK SHALL CONSIST OF:

16 (I) A STATE CRIMINAL HISTORY RECORDS CHECK FOR THE  
17 APPLICANT'S STATE OF RESIDENCE; AND

18 (II) A NATIONAL CRIMINAL HISTORY RECORDS CHECK.

19 (4) THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE  
20 SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL  
21 REQUEST THE APPROPRIATE ENTITY IN THE APPLICANT'S STATE OF RESIDENCE  
22 TO FORWARD THE RESULTS OF THE CRIMINAL HISTORY RECORDS CHECK TO  
23 THE BOARD AND THE APPLICANT.

24 (5) THE BOARD SHALL ENSURE THAT INFORMATION OBTAINED  
25 UNDER THIS SUBSECTION:

26 (I) IS KEPT CONFIDENTIAL;

27 (II) IS NOT REDISSEMINATED; AND

28 (III) IS USED ONLY FOR THE PERMITTING PURPOSE  
29 AUTHORIZED BY THIS SUBTITLE.

30 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
31 October 1, 2012.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.